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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/541,376	03/31/2000	Robert Justice Shartle	LFS-105	3494

7590 05/21/2002

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EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1743	4

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/541,376	Applicant(s) SHARTLE, ROBERT JUSTICE
	Examiner Maureen M. Wallenhorst	Art Unit 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The date the declaration was signed by the inventor is missing.

2. The disclosure is objected to because of the following informalities: On line 4 of claim 2, the phrase "stop junctions" should be changed to –the stop junctions—or –said stop junctions— in order to make proper sense. On line 3 of claim 8, the phrase "each such alternate path" should be changed to –each additional path—so as to use the same terminology as recited earlier in the claim. On lines 1-2 of claim 9, the phrase "a first alternate path" should be changed to –a first additional path--. On line 3 of claim 9, the phrase "a second alternate path" should be changed to –a second additional path-- so as to use the same terminology as recited in claim 8. This same change should also be made on lines 2 and 4 of claim 10.

Appropriate correction is required.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al (US Patent no. 6,001,307) in view of Columbus (US Patent no. 4,426,451, both submitted in the Information Disclosure Statement filed July 3, 2000).

Naka et al teach of a device for analyzing a sample, which comprises a body 5 having a base member 5b and a cover 5a. In the upper surface of the base member is located a sample inlet 4, a first capillary channel 2a for conveying a sample from the inlet to a branching point 6a (see Figures 3, 4, 5a-5d), an analytical section 3 which contains therein a reagent for reacting with the sample and which serves as a first stop junction, a second capillary channel 2b, and a suction pressure generating chamber 1. A bypass channel 6 branches from a portion of the drawing channel 2a between the opening 4 and the analytical section 3, and extends to communicate with the suction pressure generating chamber 1. The device is formed by the lamination of a plurality of films that contain cutouts therein. See Figure 10. The cutouts in the layers form the sample inlet, channels, measurement area, and bypass channel. Naka et al teach that some layers of the device can be transparent to facilitate the optical measurement of the sample therein. Naka et al fail to teach that there is a second stop flow junction in the bypass channel that forms an angle that points toward the sample inlet channel of the device.

Columbus teaches of a multi-zoned reaction vessel having pressure-actuatable control means between zones. The reaction vessel 20 comprises a first zone 22 fluidly connected by passageway 60 to an adjacent zone 24. A sample to be analyzed is introduced into the device through a liquid inlet aperture 46. A reagent is present in the first zone 22 to react with the

sample. A stop flow junction 60 is present between the first zone 22 and the second zone 24 to control the liquid meniscus by temporarily stopping the sample from flowing from zone 22 to zone 24 in order to allow the sample time to react with the reagent in zone 22. The stop flow junction has an angle formed by sidewall surfaces 32 and 34 that extend from edges 62 of the junction into zone 24. Therefore, the angle points towards the first zone 22. This configuration of the stop flow junction aids in the emptying of all of the liquid in zone 22 into zone 24. The sidewalls 32 and 34 diverge into zone 24 from passageway 60 with a constantly increasing spacing or at an increasing rate. See Figures 1, 10, 14 and 15 in Columbus.

Based upon the combination of Naka et al and Columbus, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the bypass channel in the device taught by Naka et al with a stop flow junction having the configuration taught by Columbus since Columbus teaches that a stop flow junction having an angle pointing towards the region from which a fluid is flowing out of serves to control and stop the flow of liquid from one region to the next until externally generated actuation pressure is applied, which in the bypass channel of the device taught by Naka et al, would prevent any fluid from flowing into the bypass channel until the first and second channels 2a and 2b containing the measurement region 3 are filled with sample to be analyzed.

6. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harding et al. (US Patent no. 6,261,519) in view of Columbus (US Patent no. 4,426,451). For a teaching of Columbus, see previous paragraphs in this Office action.

Harding et al teach of a medical diagnostic device that permits the measurement of analyte concentration or a property of a biological sample, particularly the coagulation time of

blood. The device comprises a first and second layer, at least one of which has a resilient region therein, separated by an intermediate layer, in which cutouts in the intermediate layer form, with the first and second layers: a) a sample port for introducing a sample of biological liquid into the device, b) a measurement area in which a physical parameter of the sample is measured and related to analyte concentration or property of the sample, c) a first channel providing a path from the sample port to the measurement area, d) a bladder at the second end of the first channel comprising at least a part of the resilient region and having a volume that is at least about equal to the combined volume of the measurement area and first channel, e) a stop junction in the first channel between the measurement area and the bladder, and f) a bypass channel that provides an additional path from the first channel to the bladder without traversing the measurement area and stop junction. See Figures 6, 6a-6f and 7 in Harding et al. The measurement area includes a reagent to react with the sample fluid. The first or second layer is substantially transparent so that the physical property which is measured is optical transmission through the measurement area. The biological fluid analyzed with the device can be whole blood, and prothrombin time can be measured. In this case, the measurement area contains thromboplastin therein. Alternate fluid paths can also be located in the device from the first channel to the bladder. Each alternate path has its own measurement area and stop junction. In the device depicted in Figure 7, the measurement area 118P contains thromboplastin. Measurement area 218 contains thromboplastin, bovine eluate and recombinant factor VIIa, which is selected to normalize the clotting time of a blood sample by counteracting the effect of an anticoagulant. Measurement area 318 contains thromboplastin and bovine eluate alone, to partially overcome the effect of an

anticoagulant. Harding et al fail to teach that there is a second stop flow junction in the bypass channel which forms an angle that points toward the first channel of the device.

Based upon the combination of Harding et al et al and Columbus, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the bypass channel in the device taught by Harding et al with a stop flow junction having the configuration taught by Columbus since Columbus teaches that a stop flow junction having an angle pointing towards the region from which a fluid is flowing out of serves to control and stop the flow of liquid from one region to the next until externally generated actuation pressure is applied, which in the bypass channel of the device taught by Harding et al, would prevent any fluid from flowing into the bypass channel until the first channel and measurement area containing the reagent are filled with sample to be analyzed.

7. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shartle et al (EP 974,840) in view of Columbus (US Patent no. 4,426,451). For a teaching of Columbus, see previous paragraphs in this Office action.

Shartle et al teach of a fluidic device for medical diagnostics having the same features and description as given above for the reference to Harding et al (US Patent no. 6,261,529). Shartle et al, however, fail to teach that there is a second stop flow junction in the bypass channel which forms an angle that points toward the first channel of the device.

Based upon the combination of Shartle et al and Columbus, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the bypass channel in the device taught by Shartle et al with a stop flow junction having the configuration taught by Columbus since Columbus teaches that a stop flow junction having an angle pointing

towards the region from which a fluid is flowing out of serves to control and stop the flow of liquid from one region to the next until externally generated actuation pressure is applied, which in the bypass channel of the device taught by Shartle et al, would prevent any fluid from flowing into the bypass channel until the first channel and measurement area containing the reagent are filled with sample to be analyzed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Shartle (US Patent no. 6,084,660, which does not qualify as a 35 USC 102(e) reference to another), Sugarman et al, Subramanian et al, Naka et al (US Patent no. 6,325,975), and Besemer et al who all teach of capillary fluidic devices containing stop flow junctions therein.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached on alternate Thursdays and every Monday and Tuesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

May 16, 2002

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP 1700